

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed March 6, 2007. Currently, claims 21-44 remain pending. Claims 21-44 have been rejected. In this amendment, claims 21, 31, 38, 43, and 44 have been amended and claims 24, 33, and 40 have been canceled. Favorable consideration of the following remarks is respectfully requested.

#### ***Claim Rejections – 35 USC § 112***

On page 2 of the Final Office Action, claim 43 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Final Office Action states that the term “the retainer” of claim 43 lacks antecedent basis. Accordingly, Applicant has amended claim 43 to recite “a retainer”. Therefore, Applicant believes that there is proper antecedent basis and respectfully requests withdrawal of the rejection.

#### ***Claim Rejections – 35 USC § 102***

On page 3 of the Final Office Action, claims 21-23, 27-29, 31-32, 34-39, and 41-44 were rejected under 35 U.S.C. 102(e) as being anticipated by Bosma et al. (U.S. Patent No. 6,241,746). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 21, which has been amended to recite:

21. (Currently Amended) A thrombus filter for placement within a blood vessel lumen defined by a blood vessel wall, comprising:  
a wall engaging portion comprised of a plurality of wall elements including a plurality of wall engaging strands;  
a filtering portion comprised of a plurality of filtering strands;  
a selectively releasable retainer disposed on the filtering strands;  
the filtering portion being fixed to the wall engaging portion;  
each wall engaging strand connected to each other wall engaging strand, either directly or solely through other wall elements; and  
a catheter disposed adjacent the thrombus filter, the catheter having a lumen and a capture member,  
wherein the catheter is configured to engage the selectively releasable retainer and the capture member is configured to retain the retainer within the lumen when the retainer has been released;

wherein the wall elements include a plurality of tubular members having central lumens, the plurality of the tubular members having a portion of at least one wall engaging strand in the central lumen.

Claim 21 has been amended to include all the limitations of claim 24, which has been canceled. In the Final Office Action, claim 24 was not rejected by Bosma et al. and, as such, is believed to be not anticipated by Bosma et al. Therefore, as amended, claim 21 is believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependant claims 22-23 and 27-29, which depend from claim 21 and include significant additional limitations, are believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 31, which has been amended to recite:

31. (Currently Amended) A thrombus filter for placement within a blood vessel lumen defined by a blood vessel wall, comprising:  
a plurality of wall engaging strands connected together and defining a generally cylindrical wall engaging portion;  
a plurality of filtering strands each having a proximal end attached to the wall engaging portion and a distal end;  
wherein the filtering strands define a filtering portion that is configured to shift between a first generally conical shape and a second generally cylindrical shape, the filtering portion being biased to be in the second generally cylindrical shape; and  
a retainer releasably attached to the distal ends of the filtering strands that holds the filtering portion in the first generally conical shape;  
wherein the retainer includes a graspable collar;  
a catheter having a lumen and a capture member, the catheter being configured to engage the retainer and the capture member being configured to retain the retainer within the lumen when the retainer has been released.

Claim 31 has been amended to include all the limitation of claim 33, which has been canceled. In the Final Office Action, claim 33 was not rejected by Bosma et al. and, as such, is believed to be not anticipated by Bosma et al. Therefore, as amended, claim 31 is believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependant claims 32 and 34-

37, which depend from claim 31 and include significant additional limitations, are believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 38, which recites:

38. (Currently Amended) A thrombus filter, comprising:  
a cylindrical wall engaging region defined by a plurality of connected wall engaging strands;  
a filtering region defined by a plurality of filtering strands each having a proximal end attached to the wall engaging portion and a distal end;  
wherein the filtering region is configured to shift between a first generally conical shape and a second generally cylindrical shape, the first generally conical shape is defined by the distal ends of the filtering strands converging and being closely associated with one another, the second generally cylindrical shape is defined by the distal ends of the filtering strands diverging and separating from one another;  
wherein the filtering region is biased to be in the second generally cylindrical shape;  
a retainer releasably attached to the distal ends of the filtering strands that holds the filtering region in the first generally conical shape, wherein the retainer includes a graspable collar; and  
a catheter configured to engage the retainer, the catheter including retaining means for maintaining the retainer within the catheter when the retainer is removed from the distal ends of the filtering strands.

Claim 38 have been amended to include the limitation of claim 40, which has been canceled. In the Final Office Action, claim 40 was not rejected by Bosma et al. and, as such, is believed to be not anticipated by Bosma et al. Therefore, as amended, claim 38 is believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, dependant claims 39 and 41-42, which depend from claim 38 and include significant additional limitations, are believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 43, which has been amended to recite:

43. (Currently Amended) A thrombus filter, comprising:  
a cylindrical wall engaging region, wherein the wall engaging region includes a plurality of tubular members having central lumens;

a filtering region having a proximal end attached to the wall engaging portion and a distal end;  
wherein the filtering region is configured to shift between a first generally conical shape and a second generally cylindrical shape, the first generally conical shape is defined when the distal end of the filtering region is closed, the second generally cylindrical shape is defined when the distal end of the filtering region is open;  
wherein the filtering region is biased to be in the second generally cylindrical shape; and  
means for controlling the shape of the filtering region releasably attached to the distal end of the filtering region;  
a catheter configured to engage ~~[[the]]~~ a retainer, the catheter including a retaining means for maintaining the means for controlling the shape of the filtering region within the catheter when the means for controlling the shape of the filtering region is released from the distal end of the filtering region.

As amended, claim 43 recites, “a cylindrical wall engaging region, wherein the wall engaging region includes a plurality of tubular members having central lumens”. Nowhere does Bosma et al. appear to teach such a limitation. Therefore, for at least this reason, claim 43 is believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 44, which has been amended to recite:

44. (Currently Amended) A thrombus filter, comprising:  
a cylindrical wall engaging portion defined by a plurality of connected wall engaging filaments;  
a filtering portion defined by a plurality of filtering filaments each having a proximal end attached to the wall engaging portion and a distal end;  
wherein the filtering portion is configured to shift between a first generally conical shape and a second generally cylindrical shape;  
wherein the filtering portion is biased to be in the second generally cylindrical shape;  
a retainer releasably attached to the distal ends of the filtering filaments that holds the filtering portion in the first generally conical shape; and  
a catheter configured to engage the retainer, the catheter including retaining means for maintaining the retainer within the catheter when the retainer is removed from the distal ends of the filtering filaments;  
wherein the wall engaging portion includes a plurality of tubular members having central lumens, the plurality of the tubular members having a portion of at least one wall engaging filament in the central lumen.

As amended, claim 44 recites, “wherein the wall engaging portion includes a plurality of tubular members having central lumens, the plurality of the tubular members having a portion of at least one wall engaging filament in the central lumen”. Nowhere does Bosma et al. appear to teach such a limitation. Therefore, for at least this reason, claim 44 is believed to be not anticipated by Bosma et al. and Applicant respectfully requests withdrawal of the rejection.

#### ***Claim Rejections – 35 USC § 103***

On page 4 of the Final Office Action, claims 21, 24-26, 30-31, 33, 38, and 40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nott et al. (U.S. Patent No. 5,709,704) in view of O’Connell (U.S. Patent No. 6,267,776). After careful review, Applicant must respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, there must at least be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. (See MPEP § 2143). The teaching or suggestion to make the claimed combination must both be found in the prior art, not in applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (See MPEP § 2143).

Nott et al. appears to disclose a blood clot filter (10) including a generally cylindrical anchoring portion (12) and a generally conical filter portion (14). The generally conical filtering portion (14) terminates at a closed, distal apical end (16). The filtering portion (14) provides a conical meshwork across the blood vessel to catch and retain clots in the blood stream. As such, the distal apical end (16) maintains the distal end of the meshwork secured together.

O’Connell discloses a filter having a retainer that can release the ends of the filter to convert to a stent-like configuration. The Examiner asserts that it would have been obvious to one of ordinary skill in the art to make Nott et al.’s retainer releasable so as to convert Nott et al. from a conical configuration to temporarily filter a blood flow and to a cylindrical configuration to deactivate the filter function of the device when filtering is no longer needed. Applicant must respectfully disagree.

As discussed above, the filter of Nott et al. specifically states that the filtering portion (14) catches and retains clots in the blood stream. (See column 4, lines 30-32). From the teachings of Nott et al., it would not be desirable to convert the filtering portion (14) from a conical shape to a cylindrical shape, which would release the clots retained in the filter, defeating the purpose of the filter. Therefore, Applicant respectfully asserts that there is no motivation found in the references to combine the teachings of Nott et al. with the retainer of O'Connell.

Furthermore, in order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). (See MPEP § 2143.03). Applicant respectfully asserts that Nott et al. and O'Connell fail to teach all the claim limitations.

Turning to claim 21, which has been amended to recite:

21. (Currently Amended) A thrombus filter for placement within a blood vessel lumen defined by a blood vessel wall, comprising:  
a wall engaging portion comprised of a plurality of wall elements including a plurality of wall engaging strands;  
a filtering portion comprised of a plurality of filtering strands;  
a selectively releasable retainer disposed on the filtering strands;  
the filtering portion being fixed to the wall engaging portion;  
each wall engaging strand connected to each other wall engaging strand, either directly or solely through other wall elements; and  
a catheter disposed adjacent the thrombus filter, the catheter having a lumen and a capture member,  
wherein the catheter is configured to engage the selectively releasable retainer and the capture member is configured to retain the retainer within the lumen when the retainer has been released;  
wherein the wall elements include a plurality of tubular members having central lumens, the plurality of the tubular members having a portion of at least one wall engaging strand in the central lumen.

Nowhere does the combination of Nott et al. and O'Connell appear to teach "a catheter disposed adjacent the thrombus filter, the catheter having a lumen and a capture member" or "wherein the catheter is configured to engage the selectively releasable retainer and the capture member is configured to retain the retainer within the lumen when the retainer has been released", as recited in claim 21.

In the Final Office Action, the Examiner acknowledges that Nott et al. does not disclose a retainer. However, the Examiner cites O'Connell as disclosing a retainer,

specifically retainer 106 and 106' of Figures 13-16. However, nowhere does Nott et al. and O'Connell disclose a catheter having a lumen and a capture member configured to engage the retainer and retain it within the lumen when it has been released.

To illustrate this, O'Connell states:

The hook 106 may be grasped by a snare or other capturing device and the releasable retainer 106 removed from the body, thereby converting the single cone filter 100 to an open, tubular stent-like configuration. The embodiment shown in FIG. 14 has a annular ring-shaped, releasable retainer 106' which may also be removed using a snare device. (Column 9, lines 2-8).

Nowhere is a catheter disclosed.

In the Final Office Action, the Examiner continues to state, "[n]aturally, the retainer 106 must be pulled out through a catheter lumen to avoid any damage to a blood vessel". From this, it appears that the Examiner is stating that it is inherent that a catheter is used. Applicant must respectfully disagree.

To establish inherency, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (See MPEP § 2112).

Accordingly, to establish inherency, it must be necessarily present in O'Connell that the retainer is retained within the catheter lumen when it is released. Applicant respectfully asserts that it is not necessarily present. The retainers 106 or 106', as disclosed by O'Connell and cited by the Examiner, are relatively small compared to the vessel and includes a rounded leading edge. With this configuration, it is possible that the retainer may be removed from the filter without the use of a catheter and without injuring the vessel. Furthermore, even if a catheter is used, the retainer may, in some

cases, not be retained in the catheter. Therefore, Applicant asserts that a catheter is not necessarily present in O'Connell.

Therefore, for at least these reasons, claim 21 is believed to be patentable over Nott et al. in view of O'Connell and Applicant respectfully requests withdrawal of the rejection. Additionally, for similar reasons, as well as others, dependant claims 24-26 and 30, which depend from claim 21 and include significant additional limitations, are believed to be patentable over Nott et al. in view of O'Connell and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 31, which has been amended to recite:

31. (Currently Amended) A thrombus filter for placement within a blood vessel lumen defined by a blood vessel wall, comprising:  
a plurality of wall engaging strands connected together and defining a generally cylindrical wall engaging portion;  
a plurality of filtering strands each having a proximal end attached to the wall engaging portion and a distal end;  
wherein the filtering strands define a filtering portion that is configured to shift between a first generally conical shape and a second generally cylindrical shape, the filtering portion being biased to be in the second generally cylindrical shape; and  
a retainer releasably attached to the distal ends of the filtering strands that holds the filtering portion in the first generally conical shape;  
wherein the retainer includes a graspable collar;  
a catheter having a lumen and a capture member, the catheter being configured to engage the retainer and the capture member being configured to retain the retainer within the lumen when the retainer has been released.

For similar reasons discussed above, as well as others, claim 21 is believed to be patentable over Nott et al. in view of O'Connell and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 38, which recites:

38. (Currently Amended) A thrombus filter, comprising:  
a cylindrical wall engaging region defined by a plurality of connected wall engaging strands;  
a filtering region defined by a plurality of filtering strands each having a proximal end attached to the wall engaging portion and a distal end;  
wherein the filtering region is configured to shift between a first generally conical shape and a second generally cylindrical shape, the first generally conical shape is defined by the distal ends of the filtering strands



converging and being closely associated with one another, the second generally cylindrical shape is defined by the distal ends of the filtering strands diverging and separating from one another;  
wherein the filtering region is biased to be in the second generally cylindrical shape;  
a retainer releasably attached to the distal ends of the filtering strands that holds the filtering region in the first generally conical shape, wherein the retainer includes a graspable collar; and  
a catheter configured to engage the retainer, the catheter including retaining means for maintaining the retainer within the catheter when the retainer is removed from the distal ends of the filtering strands.

For similar reasons discussed above, as well as others, claim 38 is believed to be patentable over Nott et al. in view of O'Connell and Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, all pending claims, namely claims 21-44, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

GARY SHAPIRO ET AL.

By their Attorney,

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